EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for 1-Bromopropane under TSCA Section 6(a)

Potential Regulatory Options

Any regulatory option could be used alone or in combination so that 1-bromopropane no longer presents an unreasonable risk under any condition of use.

Existing Chemical Exposure Limit (ECEL)

- What is an ECEL?
  - A risk management option similar to a PEL, for industrial and most commercial conditions of use. Establishes a performance-based setting and is non-prescriptive, thus enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace. Industries are already familiar with PELs, and methods of compliance.
  - An ECEL would be calculated based on the identified hazard of the chemical, such as the human equivalent concentration or the inhalation unit risk determined in the risk evaluation, and would consider the most sensitive endpoint.
  - The ECEL is the air concentration that would address unreasonable risk under any condition of use to workers or ONUs, including susceptible subpopulations.
  - An ECEL for 1-BP may be similar to the recommended level by the American Conference of Government Industrial Hygienists.

- How could it be applied?
  - If EPA sets an ECEL, businesses could meet the ECEL by changing their process or formula, using different equipment, using PPE, substituting the chemical, or some combination.
  - The decision on how to meet the ECEL is up to the business; however, an ECEL might require monitoring and recordkeeping to demonstrate compliance.

Prescriptive PPE Controls

- A risk management option that would require use of specific PPE to minimize exposure. This may limit flexibility for the regulated entity.
- PPE was considered in the unreasonable risk determination and in some cases was insufficient to address unreasonable risk.
- For example, for workers under conditions of use where unreasonable risk is still present with APF 50, EPA could require use of APF 1,000 respirators (not a preferred approach).
- For example, for ONUs under conditions of use with unreasonable risk, EPA could require ONUs to wear respirators.

Prescriptive Administrative Controls

- A risk management option that would prescribe administrative controls to reduce exposure.
- Examples:
    - Prohibit ONU access to the work area where the chemical is being handled.
    - Limit the amount of time workers handle the chemical.

Prescriptive Engineering Controls

- A risk management option that would prescribe engineering controls, such as removing a hazardous substance through air ventilation with a specific air exchange rate or to a specific air concentration limit.
- Examples:
    - Install new equipment to reduce the exposure to the chemical.
    - Install or upgrade ventilation systems to help control and/or eliminate air contaminants.
    - Enclose or confine operations to avoid or reduce employee exposure.

Concentration Limit

- A risk management option that would restrict the concentration or weight fraction within the formulation (e.g., limit the amount of the chemical in the formulation to 10%).
- However, a concentration limit may impact the efficacy of a product.

Regulate the Manufacturing, Processing, and/or Distribution

- A risk management option for consumer conditions of use. These authorities allow EPA to regulate at key points in the supply chain.

Prohibition

- A risk management option for conditions of use where ECEL, PPE, engineering controls, administrative controls, and/or concentration limit are not feasible or sufficient, or for conditions of use that have minimal ongoing use or have been phased out.

Examples of combinations of regulatory options

- A risk management option that would prescribe engineering and PPE to reduce exposure.

    - For example, EPA could mandate use of specific ventilation rate to reduce exposure as much as possible and then evaluate respirator selection to eliminate unreasonable risk.
- A risk management option that would require prescriptive engineering, PPE, and administrative controls to reduce exposure.
    - For example, EPA could require use of specific equipment and PPE to reduce exposure to workers and then limit access to the work area to eliminate the unreasonable risk to ONUs.
- A risk management option that would set a maximum require reduction concentration limit and require engineering controls.
    - For example, require reduction of concentration in the product and then require use of a specific ventilation system to eliminate unreasonable risk.

Regulatory options applied broadly with other restrictions

- Recordkeeping and downstream notification
    - For example, EPA could require manufacturers, processors, and distributors to provide downstream notification to help ensure regulatory information reaches all users in the supply chain.
    - Require manufacturers, processors, and distributors to maintain ordinary business records.
- Monitoring and labeling
    - For example, EPA could require provide a prominent label securely attached to each container with specific directions, limitations, and precautions, or that describes the health endpoints.
    - Require initial or periodic monitoring of occupational exposure.
- Limited access program
    - For example, restrict distribution of a chemical or product only to certain users, under a limited access program that could require training and certification.

Costs of Regulatory Options

Type of Cost	Estimated Compliance Cost	Notes
Existing Chemical Exposure Limit (ECEL)	Unknown	Identifying specific requirements requires input from potentially regulated entities.
Personal Protective Equipment (PPE) – Inhalation exposure (respirators)	APF 25: $1,200 APF 50: $500-$2,000 APF 1000: $600-$1,300 APF10000: $1,700-$2,000 *See separate handout for detailed breakdown*	Costs are per employee and include purchase of equipment (including filters), training, fit-testing, and medical clearance. Does not include existing PPE use nor PPE replacement due to employee turn-over.
Personal Protective Equipment (PPE) – Dermal Exposure (gloves)	1-BP-resistant gloves range from $7.03 to $42.25 per pair	For tasks that don't subject the gloves to mechanical damage, the $7.03 (laminate film) gloves would likely be protective for an entire shift. More expensive gloves ($30/pair - PVA) might be needed for tasks that subject gloves to mechanical damage and 1-BP exposure. 1-BP-resistant gloves can typically be used for an entire shift if used properly and not torn.
Engineering/Administrative Controls	Varies by control type and needs of user	Identifying specific requirements requires input from potentially regulated entities.
Reformulation of product to reduce or eliminate 1-BP concentration	$13,000-$129,000 per product	Costs will vary by condition of use and will be dependent on reformulation approach. Requires input from potentially regulated entities.
Product Label or Warnings	$750 - $8,000 per product	Costs will vary by condition of use. Potential activities may include graphic design changes, plate changes, discarded inventory, and labor.
Substitute Products (average per ounce)	Varies with condition of use	1-BP is expected to be less expensive per ounce than most drop-in substitutes. However, 1-BP may be more expensive than some substitutes that involve changes in engineering controls (e.g. use of flammable solvents as substitutes).
Substitute Methods	Varies by job labor rate	This will primarily be labor cost and cost of alternative equipment (i.e. a heat gun).
Recordkeeping	$200-$325 per firm	Annual labor and material costs associated with documentation of ordinary business records.
Downstream Notification	$112-$125 per product	Costs are per product and include labor and material costs to update the product's safety data sheet (SDS).
Product Label or Warnings	$750 - $8,000 per product	Costs will vary by condition of use. Potential activities may include graphic design changes, plate changes, discarded inventory, and labor.